

IN THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claim 1 (original). A retractor for manipulating an object, comprising:

a body having proximal and distal ends;

a retraction device having:

a head connected to said distal end of said body;

a connector movably disposed in said body; and

flexible needles of a shape memory material having a memory shape, said needles connected to said connector, said memory shape of said needles including a portion with an arcuate shape; and

an actuation device connected to said proximal end of said body and operatively connected to said connector through said body, said actuation device, upon actuation thereof, moving said connector to selectively extend said needles out of said head and withdraw said needles into said head.

Claim 2 (original). The retractor according to claim 1, wherein:

said body has a longitudinal extent defining a longitudinal direction; and

said needles extend out of said head in a direction substantially orthogonal to said longitudinal direction.

Claim 3 (original). The retractor according to claim 1, wherein said head is connected removably to said distal end of said body.

Claim 4 (original). The retractor according to claim 1, wherein said head is integrally formed with said body.

Claim 5 (original). The retractor according to claim 1, wherein:

said head defines tracks for respective ones of said needles; and
said tracks have track exits open to the environment.

Claim 6 (original). The retractor according to claim 5, wherein said track exits open in a direction at an angle to said longitudinal direction.

Claim 7 (original). The retractor according to claim 5, wherein said track exits open in a direction substantially orthogonal to said longitudinal direction.

Claim 8 (original). The retractor according to claim 5, wherein said track exits are disposed to permit movement of said needles therethrough substantially without friction.

Claim 9 (original). The retractor according to claim 5, wherein said track exits are disposed on opposing sides of said head and said tracks guide said needles through said track exits.

Claim 10 (original). The retractor according to claim 8, wherein at least one surface of said tracks guide said needles in a direction substantially orthogonal to a movement direction of said connector.

Claim 11 (original). The retractor according to claim 5, wherein:
said needles have a needle diameter; and
said track exits have a diameter at least as large as said needle diameter.

Claim 12 (original). The retractor according to claim 5, wherein said tracks have a shape corresponding to said memory shape of a portion of said needles.

Claim 13 (original). The retractor according to claim 12, wherein said memory shape of said needles includes a substantially linear proximal portion and an arcuate distal portion.

Claim 14 (original). The retractor according to claim 13, wherein said shape of said

SYN-8312

3 of 24

10/728,389

tracks corresponds to said memory shape of said proximal portion and to said memory shape of a portion of said distal portion.

Claim 15 (currently amended). The retractor according to claim 5, wherein said head has two head halves clamping said needles therebetween.

Claim 16 (original). The retractor according to claim 15, wherein said two halves are removably connected to one another.

Claim 17 (original). The retractor according to claim 15, wherein said head has a shim disposed between said two halves.

Claim 18 (original). The retractor according to claim 15, wherein said two halves define said tracks.

Claim 19 (currently amended). The retractor according to claim 15, wherein said two halves and a said shim define said tracks.

Claim 20 (original). The retractor according to claim 15, wherein:

said connector is movably disposed in at least one of said head and said body;

said needles each have a proximal portion and a distal portion; and

said memory shape of said proximal portion is substantially linear and said memory shape of said distal portion has said arcuate shape.

Claim 21 (original). The retractor according to claim 1, wherein said arcuate shape of said portion is no greater than a circle.

Claim 22 (original). The retractor according to claim 1, wherein said arcuate shape of said portion is greater than a semi-circle.

Claim 23 (original). The retractor according to claim 1, wherein said needles are two needles.

SYN-8312

4 of 24

10/728,389

Claim 24 (original). The retractor according to claim 1, wherein said material is at least one of the group consisting of a pseudo-elastic metal, nitinol, and a Nickel-Titanium alloy.

Claim 25 (original). The retractor according to claim 1, wherein said actuation device is connected removably to said proximal end of said body.

Claim 26 (original). The retractor according to claim 1, wherein:
said body has a coil winding and an outer jacket surrounding said coil winding;
and
said connector is movably disposed in said coil winding.

Claim 27 (original). The retractor according to claim 1, wherein said retraction device grasps the object upon extension of said needles out of said head and releases the object upon withdrawal of said needles into said head.

Claim 28 (original). The retractor according to claim 1, wherein:
said actuation device has a rod; and
said rod passes through said body and is connected to said connector for moving said connector.

Claim 29 (original). The retractor according to claim 28, wherein said rod is integrally formed with said connector.

Claim 30 (original). The retractor according to claim 28, wherein said rod is removably connected to said connector.

Claim 31 (original). The retractor according to claim 1, further comprising a proximal stop disposed in said body and limiting a retraction range of said needles.

Claim 32 (original). The retractor according to claim 1, wherein said actuation device

has a locking device selectively retaining said needles in a given position.

Claim 33 (original). The retractor according to claim 32, wherein said locking device selectively retains said needles in an extended position.

Claim 34 (original). The retractor according to claim 1, wherein said actuation device has an overstroke preventor limiting an extension distance of said needles out of said head.

Claim 35 (original). The retractor according to claim 1, wherein said actuation device is a one-handed actuation device.

Claim 36 (original). The retractor according to claim 1, wherein said head has an anchoring spike retaining said head at a user-selected placement position.

Claim 37 (original). The retractor according to claim 1, wherein said body is a flexible body.

Claim 38 (original). The retractor according to claim 1, wherein said body is a rigid body.

Claim 39 (original). In combination with a flexible endoscope having at least one working channel, a tissue retractor for manipulating tissue inside a patient, comprising:

- a body having proximal and distal ends;

- a retraction device having:

- a head connected to said distal end of said body;

- a connector movably disposed in said body; and

- flexible needles of a shape memory material having a memory shape, said needles connected to said connector, said memory shape of said needles including a portion with an arcuate shape; and

- an actuation device connected to said proximal end of said body and operatively connected to said connector through said body, said actuation device, upon actuation

thereof, moving said connector to selectively extend said needles out of said head and withdraw said needles into said head;
wherein said body and said retraction device are sized to fit within the working channel of the endoscope.

Claim 40 (original). The retractor according to claim 39, wherein said needles are sized to selectively grasp alimentary tract tissue.

Claim 41 (original). The retractor according to claim 39, wherein said needles are sized to extend into mucosa without extending into muscularis.

Claim 42 (original). The retractor according to claim 39, wherein said needles are sized to extend through mucosa and into muscularis.

Claim 43 (original). The retractor according to claim 39, wherein said needles are sized to extend into mucosa and muscularis without extending into serosa.

Claim 44 (original). The retractor according to claim 39, wherein said needles are sized to selectively extend through different layers in the gastric wall.

Claim 45 (original). The retractor according to claim 39, wherein:
said head defines openings on opposing sides thereof; and
said memory shape of said needles curves said needles away from opposing sides of said connector.

Claim 46 (original). The retractor according to claim 39, wherein:
said body has a longitudinal extent defining a longitudinal direction; and
said needles extend out of said head in a direction substantially orthogonal to said longitudinal direction.

Claim 47 (original). The retractor according to claim 39, wherein said head is connected removably to said distal end of said body.

SYN-8312

7 of 24

10/728,389

Claim 48 (original). The retractor according to claim 39, wherein said head is integrally formed with said body.

Claim 49 (original). The retractor according to claim 39, wherein:
said head defines tracks for respective ones of said needles; and
said tracks have track exits open to the environment.

Claim 50 (original). The retractor according to claim 49, wherein said track exits open in a direction at an angle to said longitudinal direction.

Claim 51 (original). The retractor according to claim 49, wherein:
said memory shape of said needles includes a substantially linear proximal portion and an arcuate distal portion; and
said tracks have a shape corresponding to said memory shape of said proximal portion and to said memory shape of a portion of said distal portion.

Claim 52 (original). The retractor according to claim 39, wherein said arcuate shape of said portion is no greater than a circle.

Claim 53 (original). The retractor according to claim 39, wherein said needles are two needles.

Claim 54 (original). The retractor according to claim 39, wherein said material is at least one of the group consisting of a pseudo-elastic metal, nitinol, and a Nickel-Titanium alloy.

Claim 55 (original). The retractor according to claim 1, wherein:
said actuation device has a rod; and
said rod passes through said body and is connected to said connector for moving said connector.

SYN-8312

8 of 24

10/728,389

Claim 56 (original). The retractor according to claim 55, wherein said rod is integrally formed with said connector.

Claim 57 (original). The retractor according to claim 55, wherein said rod is removably connected to said connector.

Claim 58 (original). The retractor according to claim 39, wherein said actuation device is a one-handed actuation device.

Claim 59 (original). The retractor according to claim 39, wherein said head has an anchoring spike retaining said head at a user-selected placement position.

Claim 60 (original). The retractor according to claim 39, wherein said body is a flexible body.

Claim 61 (original). The retractor according to claim 39, wherein said body is a rigid body.

Claim 62 (original). The retractor according to claim 39, further comprising a proximal stop disposed in said body and limiting a retraction range of said needles.

Claim 63 (original). The retractor according to claim 39, wherein said actuation device has a locking device selectively retaining said needles in a given position.

Claim 64 (original). The retractor according to claim 63, wherein said locking device selectively retains said needles in an extended position.

Claim 65 (original). The retractor according to claim 39, wherein said actuation device has an overstroke preventor limiting an extension distance of said needles out of said head.

SYN-8312

9 of 24

10/728,389

Claim 66 (original). A tissue retractor, comprising:

- a body having proximal and distal ends;

- a retraction device having:

 - a head connected to said distal end of said body and defining two opposing openings;

 - a connector movably disposed in said body; and

 - flexible needles of a shape memory material having a memory shape, said needles connected to said connector, said memory shape of said needles including a portion with an arcuate shape; and

 - a one-handed actuation device connected to said proximal end of said body and operatively connected to said connector through said body, said actuation device, upon actuation thereof, moving said connector to selectively extend said needles out of said head and withdraw said needles into said head.

Claim 67 (withdrawn). A method for retracting tissue, which comprises:

- positioning a flexible endoscope having at least one working channel adjacent a location of tissue to be retracted;

- passing the tissue retractor according to claim 1 through the working channel of the endoscope;

 - positioning the head of the retractor at a desired retraction location on the tissue;

 - actuating the actuation device to extend the needles into the tissue at the desired retraction location; and

 - retracting the tissue with the retractor.

Claim 68 (withdrawn). The method according to claim 67, which further comprises actuating the actuation device to retract the needles back into the head to release the tissue.

Claim 69 (withdrawn). A method for retracting tissue, which comprises:

- positioning the endoscope according to claim 39 adjacent a location of tissue to be retracted;

- passing the tissue retractor through the working channel of the endoscope;

SYN-8312

10 of 24

10/728,389

positioning the head of the retractor at a desired retraction location on the tissue;
actuating the actuation device to extend the needles into the tissue at the
desired retraction location; and
retracting the tissue with the retractor.

Claim 70 (withdrawn). The method according to claim 69, which further comprises
actuating the actuation device to retract the needles back into the head to release the
tissue.

Claim 71 (withdrawn). A method for retracting tissue for the treatment of
Gastroesophageal Reflux Disease, which comprises:

positioning a flexible endoscope having at least one working channel adjacent a
desired retraction location of the wall of the stomach;
passing the tissue retractor according to claim 1 through the working channel of
the endoscope;
positioning the head of the retractor on the desired retraction location of the
stomach wall;
actuating the actuation device to extend the needles into the stomach wall at the
desired retraction location; and
retracting the stomach wall with the retractor.

Claim 72 (withdrawn). The method according to claim 71, which further comprises
shaping a curvature of the needles to limit penetration of the stomach wall to a depth no
greater than the muscularis.

Claim 73 (withdrawn). The method according to claim 71, which further comprises:

providing a clip implantation and plication instrument having a proximal actuating
handle and a distal end effector with jaws, the jaws containing male and female parts of
a plication fastener;
positioning the end effector adjacent the retracted stomach wall;
operating the proximal actuating handle to cause the jaws of the end effector to
open;

SYN-8312

11 of 24

10/728,389

pulling the retracted stomach wall between the opened jaws of the end effector;
operating the actuation handle to cause the jaws to close about the retracted stomach wall while holding a substantially central point of the stomach wall between the jaws with the retractor and form a tissue plication with the jaws as the male and female parts of the fastener are brought together with the plication clamped therebetween;
when the jaws are closed about the plication, deploying the fastener to pierce the plication with the male part of the fastener through the serosal layers of the plication forming a serosa-to-serosa contact on the inside surfaces of the plication;
determining the location and size of the plication and relative position of the fastener parts with the endoscope and:
if a satisfactory Implantation is determined, operating the proximal actuation handle to lock the male and female parts of the fastener and to release the locked fastener from the jaws; and
if a satisfactory implantation is not determined, re-opening and re-orienting the jaws to form another plication until a satisfactory implantation is determined and, then, operating the proximal actuation handle to lock the male and female parts of the fastener and release the locked fastener from the jaws;
opening the jaws; and
withdrawing the clip implantation and plication instrument and the endoscope through the esophagus and out of the patient.

Claim 74 (withdrawn). The method according to claim 73, which further comprises:

approaching the retracted stomach wall with the jaws in a direction substantially parallel to the esophagus; and
forming the plication substantially parallel to the esophagus.

Claim 75 (withdrawn). A method for retracting tissue for the treatment of Gastroesophageal Reflux Disease, which comprises:

positioning the endoscope according to claim 39 adjacent a desired retraction location of the stomach wall of the stomach;
passing the tissue retractor through the working channel of the endoscope;
positioning the head of the retractor on the desired retraction location of the

stomach wall;

actuating the actuation device to extend the needles into the stomach wall at the desired retraction location; and

retracting the stomach wall with the retractor.

Claim 76 (withdrawn). The method according to claim 75, which further comprises shaping a curvature of the needles to limit penetration of the stomach wall to a depth no greater than the muscularis.

Claim 77 (withdrawn). The method according to claim 75, which further comprises:

providing a clip implantation and plication instrument having a proximal actuating handle and a distal end effector with jaws, the jaws containing male and female parts of a plication fastener;

positioning the end effector adjacent the retracted stomach wall;

operating the proximal actuating handle to cause the jaws of the end effector to open;

pulling the retracted stomach wall between the opened jaws of the end effector;

operating the actuation handle to cause the jaws to close about the retracted stomach wall while holding a substantially central point of the stomach wall between the jaws with the retractor and form a tissue plication with the jaws as the male and female parts of the fastener are brought together with the plication clamped therebetween;

when the jaws are closed about the plication, deploying the fastener to pierce the plication with the male part of the fastener through the serosal layers of the plication forming a serosa-to-serosa contact on the inside surfaces of the plication;

determining the location and size of the plication and relative position of the fastener parts with the endoscope and:

if a satisfactory implantation is determined, operating the proximal actuation handle to lock the male and female parts of the fastener and to release the locked fastener from the jaws; and

if a satisfactory implantation is not determined, re-opening and re-orienting the jaws to form another plication until a satisfactory implantation is determined and, then, operating the proximal actuation handle to lock the male

SYN-8312

13 of 24

10/728,389

and female parts of the fastener and release the locked fastener from the jaws;
opening the jaws; and
withdrawing the clip implantation and plication instrument and the endoscope
through the esophagus and out of the patient.

Claim 78 (withdrawn). The method according to claim 77, which further comprises:
approaching the retracted stomach wall with the jaws in a direction substantially
parallel to the esophagus; and
forming the plication substantially parallel to the esophagus.

Claim 79 (withdrawn). The method according to claim 67, which further comprises:
providing the retractor with a removable handle; and
removing the handle after the needles are extended into the tissue.

Claim 80 (withdrawn). The method according to claim 79, which further comprises
guiding a second endoscope over the body of the retractor towards the head of the
retractor.

Claim 81 (withdrawn). The method according to claim 69, which further comprises:
providing the retractor with a removable handle;
removing the handle after the needles are extended into the tissue; and
guiding a second endoscope over the body of the retractor towards the head of
the retractor.

Claim 82 (withdrawn). A method for grasping an object, which comprises:
positioning the head of the retractor according to claim 1, at a desired location on
the object;
actuating the actuation device to extend the needles into the object at the
desired location to grasp the object with the retractor.

Claim 83 (original). The retractor according to claim 1, wherein said actuation device,
upon actuation thereof, moves said actuator to selectively extend said needles out of

said head into tissue of a patient and withdraw said needles from the tissue into said head.

Claim 84 (original). The retractor according to claim 1, wherein said needles are sized to control penetration depth through tissue.

Claim 85 (original). The retractor according to claim 1, wherein said needles are fixedly connected to said connector.

Claim 86 (original). The retractor according to claim 39, wherein said needles are fixedly connected to said connector.

Claim 87 (original). The retractor according to claim 66, wherein said needles are fixedly connected to said connector.